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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/832,729      | 04/09/2001  | Robert F. Baugh      | P9520               | 9763             |

7590

10/10/2003

Steven C Petersen for Hogan & Hartson LLP  
One Tabor Center  
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EXAMINER

DESANTO, MATTHEW F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3763

DATE MAILED: 10/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

08

# Office Action Summary

Application No.

09/832,729

Applicant(s)

BAUGH ET AL.

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 14-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### DETAILED ACTION

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "mixing chamber, filter, and restoration agent" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 14-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitmore (USPN 6,197,194) and further in view of Iwasaki (USPN 5,807,344).

Whitmore discloses a system for preparing autologous plasma and fibrin gel, wherein the system consists of two vessel, each vessel with its out chamber, a means for drawing a liquid into and out of the vessels, as well as filters (48) means outside the vessels and a mixing chamber [or a lumen connecting the two vessels] (28), but fails to disclose valve means, a restoration agent, a filter position within the vessel, and an activation member within the vessel. (Figures 1,2 and entire reference)

Iwasaki discloses a syringe with a restoration agent such as calcium salt, an activation agent such as glass wool, plastic, or silica aluminum, and a filter wherein the filter can be the activation agent. (Figure1, 3-5 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the disclosed invention of Whitmore with the specific syringe of Iwasaki because Whitmore discloses a system for making a plasma gel, but fails to disclose the specific agents as disclosed in Iwasaki. The motivation to combine is that it is well known in the art when drawing blood to have these features such as a restoration agent, an activation agent and a filter in the syringe. It is also well known in the catheter art, to use a valve to control fluid flow from the end of a syringe. The reason for placing the Iwasaki syringe in place of one of the syringes in Whitmore is because the Iwasaki allows for obtaining blood and keeping it as a sample.

3. Claims 14-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitmore (USPN 6,197,194) and further in view of Eisenhardt et al. (USPN 4,687,000).

Whitmore discloses a system for preparing autologous plasma and fibrin gel, wherein the system consists of two vessel, each vessel with its out chamber, a means for drawing a liquid into and out of the vessels, as well as filters (48) means outside the vessels and a mixing chamber [or a lumen connecting the two vessels] (28), but fails to disclose valve means, a restoration agent, a filter position within the vessel, and an activation member within the vessel. (Figures 1,2 and entire reference)

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Eisenhardt et al. discloses a syringe with a restoration agent such as calcium salt, an activation agent such as glass wool, plastic, or silica aluminum, and a filter wherein the filter can be the activation agent. (Figure 1-3 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the disclosed invention of Whitmore with the specific syringe of Eisenhardt et al. because Whitmore discloses a system for making a plasma gel, but fails to disclose the specific agents as disclosed in Iwasaki. The motivation to combine is that it is well known in the art when drawing blood to have these features such as a restoration agent, an activation agent and a filter in the syringe. It is also well known in the catheter art, to use a valve to control fluid flow from the end of a syringe.

4. Claims 14-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitmore (USPN 6,197,194) and further in view of Tabata et al. (USPN 6,511,439).

Whitmore discloses a system for preparing autologous plasma and fibrin gel, wherein the system consists of two vessel, each vessel with its out chamber, a means for drawing a liquid into and out of the vessels, as well as filters (48) means outside the vessels and a mixing chamber [or a lumen connecting the two vessels] (28), but fails to disclose valve means, a restoration agent, a filter position within the vessel, and an activation member within the vessel. (Figures 1,2 and entire reference)

Tabata et al. discloses a syringe with a restoration agent such as calcium salt, an activation agent such as glass wool, plastic, or silica aluminum, and a filter wherein the filter can be the activation agent. (Figure 1,7,8,9 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the disclosed invention of Whitmore with the specific syringe of Tabata et al. because Whitmore discloses a system for making a plasma gel, but fails to disclose the specific agents as disclosed in Iwasaki. The motivation to combine is that it is well known in the art when drawing blood to have these features such as a restoration agent, an activation agent and a filter in the syringe. It is also well known in the catheter art, to use a valve to control fluid flow from the end of a syringe.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 14-28 have been considered but are moot in view of the new ground(s) of rejection.
6. The examiner would appreciate if the Applicant could give reference numbers to the structural limitations of the claimed invention, because the examiner cannot find some of the elements in the drawings.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.



Matthew DeSanto  
Art Unit 3763  
October 6, 2003



BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
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